

TUFTS UNIVERSITY

**Report and Recommendations Concerning the Relationship of  
the Sackler Family and Purdue Pharma with Tufts University**

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## **Executive Summary**

There is no real dispute that there is an opioid crisis in the U.S., resulting in countless deaths, scores of people who remain addicted, wrecked lives, broken families and wounded communities. Still, there is some disagreement as to the dominant cause: pharmaceutical companies that illegally market their products, illegal drug pushers, drug wholesalers inattentive to red flags of questionable orders, willfully blind or unscrupulous prescribers, or inept and timid regulators. Some would say, “all of the above.”

As the crisis unfolded and worsened, victims and regulators appropriately sought to assess blame and seek accountability. Inevitably, the focus was on the pharmaceutical companies that sold opioids, including (but not exclusively) Purdue Pharma (“Purdue”). No doubt this is because Purdue aggressively marketed OxyContin, in some instances illegally, seemingly oblivious to the consequences. Also, Purdue is privately owned by members of the Sackler family, who reportedly reaped billions of dollars. So, they were and remain a prime target of harsh criticism, regulators, and lawsuits.

At the same time, Purdue and the Sackler family were long-time generous donors to universities, medical institutions, museums, and other charitable causes. The Sackler name has been displayed at the Metropolitan Museum of Art and the Guggenheim Museum in New York, the Louvre in Paris and many elite universities, including Tufts University. This dichotomy prompted questions about their motives and the propriety of the relationships.

It is against this background that we were asked to conduct this review. Tufts University, over many years, solicited and received donations from the Sacklers and, to a lesser extent, Purdue. Questions raised in the last few years about that relationship and the wisdom of continuing to accept such funds were heightened by the civil complaint filed by the Massachusetts Attorney General in January 2019. The complaint alleged, among other things,

that Purdue and the Sacklers had used the relationships with Tufts and other educational and medical institutions to burnish their image and further their business interests. Moreover, it implied that through these gifts and grants, Purdue was able to influence the activities of these institutions. That question of influence became the focus of our review, to determine whether there was any impact, real or perceived, on the independence, academic integrity or appropriate role of Tufts.

There is another context of our review. Increasingly, charitable organizations of every stripe have been confronted with questions about donations from certain sources. Whether these gifts were given long ago or more recently, the fundamental issue is similar: What is the right balance between a university's need to generate donations to support its mission of educating students and advancing research, while remaining true to its values and avoiding reputational harm?

These are not always easy decisions. And, the issues are not susceptible to bright lines. Even in the case of Purdue, we do not feel that we have access to all the facts necessary to determine with precision its role in the opioid crisis. We leave that to the regulators and the judicial process. We have, however, taken a close look at the relationship between Purdue, the Sacklers, and Tufts.

As detailed in this Report, we determined that the funds received by Tufts from the Sacklers and Purdue were predominately used in areas unrelated to opioids and pain management. Even where there was a relationship, particularly in Purdue's funding of the Master's degree program in Pain Education, Research and Policy at the Tufts University School of Medicine, we found no evidence that the funds materially affected or skewed the academic program. Yet, we do believe that Purdue intended to use the relationship with Tufts to advance

its own interests and, in a few particular instances, there is some evidence that it was successful in exercising influence, whether directly or indirectly. Moreover, we conclude that there was an appearance of too close a relationship between Purdue, the Sacklers, and Tufts. This donor relationship existed and continued in the face of growing evidence and concern about Purdue's role in marketing opioids, without the necessary scrutiny and due diligence.

Thus, we are recommending a variety of steps for Tufts to consider to ensure greater uniformity and coherence of its policies covering major gifts and grants. These recommendations include the appointment of a university-wide Chief Compliance Officer, the adoption of standard guidelines and conflict-of-interest policies across the University, additional training on conflicts of interest, and enhanced visibility to the University's confidential hotline for reporting ethics or policy violations.

We are also recommending increased formality and due diligence with respect to gifts and donations. These include the creation of a high-level, university-wide Gifts Policy Committee, enhanced due diligence concerning donations (particularly related to certain areas, like public health), and more thorough review in granting honorary degrees. The Gifts Policy Committee would review major gifts, including the sources of the gift, the purposes, and whether those gifts should be accepted in instances when the donor requests anonymity. Indeed, in order to be more transparent, Tufts should establish a baseline set of explicit conditions and restrictions on any donations and publicize those to potential donors and the University community. Any variance from these conditions/restrictions should be done sparingly and only with the approval of the Gifts Policy Committee.

Finally, we are suggesting a series of measures to ensure that the necessary boundaries be respected and that necessary scrutiny be applied with respect to the appointment of certain

adjunct faculty, any connection with the sales or marketing of a product, and any use of faculty affiliations in commercial settings.

## **I. Background of Investigation**

In February 2019, Tufts engaged Yurko, Salvesen & Remz, P. C. (“YSR”)<sup>1</sup> to conduct a review of the relationship between the University and the Sackler family and Purdue,<sup>2</sup> with a focus on whether these relationships resulted in any improper influence on Tufts’ academic or research endeavors. The review had a particular, but not exclusive, focus on pain management and opioid use and abuse and on the program known as the Master’s of Science in Pain Research, Education and Policy (“PREP”). We were also asked to provide recommendations as to whether new or modified policies or practices should be adopted, particularly those governing relationships between the University and its donors.

The catalyst for the investigation and review was the public disclosure in January 2019 of the complete unredacted Amended Complaint filed by the Attorney General of Massachusetts in Massachusetts Superior Court against Purdue, certain members of the Sackler family and certain officers of Purdue. The Amended Complaint contains a number of allegations concerning the relationship between Purdue/Sackler and Tufts. Although the Amended Complaint does not name Tufts as a defendant or accuse it of wrongdoing, it alleges that Purdue/Sackler attempted improperly to influence Tufts’ academic programs and research at the Tufts University School of Medicine (“TUSM”), including the PREP program.<sup>3</sup>

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<sup>1</sup> The review was done by former U.S. Attorney Donald K. Stern and Attorney Sanford F. Remz, neither of whom had previously performed any services for Tufts.

<sup>2</sup> “Purdue” includes Purdue Pharma LLP, Purdue Pharma, Inc. and The Purdue Frederick Company.

<sup>3</sup> We note that Tufts Medical Center (“TMC”), though affiliated, is independent from Tufts University. Tufts Health Plan is entirely independent and unaffiliated with Tufts University. As a result, we did not examine any financial relationships or other relationships between Purdue/Sackler and those separate entities. We also note that some (but by no means all) of the allegations in the Commonwealth’s Amended Complaint refer to those independent entities

YSR performed the following steps in its fact-finding investigation:

- Reviewed Tufts’ internal documents, including emails, contracts, memoranda, faculty records, meeting minutes, conflict-of-interest records, policies governing conflicts of interest and research, University Advancement department records, program and curricula descriptions, course syllabi, web pages, faculty lists, student lists, lecture content and other related records
- Reviewed records in the public domain concerning Purdue, members of the Sackler family, opioids and related matters, including professional articles, news articles, and records of legal proceedings concerning Purdue and the Sacklers
- Reviewed policies of other organizations and of recommended best practices relating to medical schools and academic medical centers
- Conducted 33 interviews of current and former Tufts and TUSM senior administrators, faculty, members of the University Advancement department, students, alumni of the PREP program, and critics, several of them over more than one session <sup>4</sup>
- Obtained and reviewed documents referenced in the Amended Complaint relating to Tufts provided to us by Purdue<sup>5</sup>
- Consulted with David Fiellin, Professor of Medicine at Yale School of Medicine and Director, Yale Program in Addiction Medicine, in order to gain a better understanding of course content and materials

At the conclusion of the fact-finding phase, YSR presented its preliminary findings and recommendations to a committee of experts for the purpose of considering any adjustments to

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and not Tufts University. For example, a reference in the Amended Complaint that a Purdue medical liaison asserted that he got two unbranded Purdue curricula approved for teaching Tufts students (Am. Comp. ¶285) actually related to a continuing medical education (“CME”) program sponsored by Tufts Health Plan (not Tufts University or TUSM) for their affiliated doctors, not TUSM students.

<sup>4</sup> We also attempted to interview Dr. David Haddox, a former Purdue senior executive who was a lecturer in the PREP program and who received appointments at TUSM as an Adjunct Assistant Professor and then Adjunct Associate Professor. However, he declined to be interviewed or to provide answers to written questions. We did not attempt to interview any of the Sacklers or other Purdue personnel, given the pendency of litigation against them in Massachusetts and around the country.

<sup>5</sup> Those documents were limited specifically to those cited in the Amended Complaint and, therefore, provided us only with limited information concerning Purdue’s conduct and intention in its relationship with Tufts. Moreover, because those documents are subject to a court-related confidentiality agreement, we are unable to make specific reference to them in this report. Nevertheless, we considered the substance of those documents in our review.

those recommendations. This ad-hoc group of experts have experience and perspectives that added to our own. They are: (1) Jeremy Sugarman, Professor of Bioethics and Medicine at the John Hopkins Berman Institute of Bioethics; (2) David Fiellin, Professor of Medicine at Yale School of Medicine and Director, Yale Program in Addiction Medicine, and (3); Melissa Mazan, Professor at the Cummings School of Veterinary Medicine at Tufts University and President of the Tufts Faculty Senate. While we certainly greatly benefited from their questions and comments, this Report is our own and is not intended necessarily to reflect any of their individual views.

YSR received full cooperation from everyone within Tufts (administration, staff, faculty) from whom we sought information or whom we interviewed. The Tufts Office of University Counsel fully supported the investigation. However, our investigation was limited by certain practical realities.

- Complete files do not go back to 1998, when the PREP proposal was first prepared. In the years since 1998, systems changed, documents were not preserved, and various categories of emails were not available for substantial periods of time.
- Certain senior people who were very involved with the Sackler/Purdue relationship and/or the establishment of the PREP program have passed away or have significant health challenges.

## **II. History of the Relationship of Tufts with the Sackler Family and Purdue**

### **A. The Sackler Family**

The philanthropic relationship between Tufts and the Sackler family began, at least in a major way, in January 1980 when brothers Arthur, Mortimer and Raymond Sackler entered into an agreement with Tufts to make a donation and to name the newly established Sackler School of Graduate Biomedical Sciences. This was many years before OxyContin was invented and then first marketed in 1996. At the time of the donation, the Sackler brothers owned together the drug

company Purdue Frederick, which later became part of Purdue. The written gift agreement specified the name of the school and how the name is to be displayed. The agreement contained no conditions as to what Tufts had to do with the money with respect to curriculum or research. The school still bears the Sackler name today.<sup>6</sup>

Thereafter, in 1983, Arthur Sackler entered into a gift agreement with Tufts to name the medical school building. The written gift agreement specified that the building was to bear the name of Arthur Sackler and that was to be the sole name associated with the building. The building still officially carries the name of Arthur Sackler today, though it is now referred to informally in TUSM communications as the Medical Education Building. The agreement contained no conditions bearing on the TUSM program, research or curriculum.

Arthur died in 1987.<sup>7</sup> Mortimer and Raymond then purchased his interest in Purdue. The two surviving brothers continued to be actively involved in Purdue, as did certain of their children.

The total donations to Tufts in the name of Sackler family members, individually or through foundations, and from Purdue have amounted to approximately \$15 million since 1980. The donations in the names of family members or foundations (in contrast to Purdue, as discussed below) were primarily for research, including cancer, neuroscience, and convergence research. None of those donations were related to opioids or pain research or programs. The major family donations since the two donations discussed above included the following:

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<sup>6</sup> At the time the donation was made, it stirred dissent among some members of faculty who questioned the sufficiency of the size of the donation. They also raised questions about the ethics of the Sacklers' business practices which, though not specified in faculty meeting minutes, may have related to certain marketing practices employed by Purdue, even prior to OxyContin. Arthur Sackler is considered one of the originators of pharmaceutical marketing and promotion.

<sup>7</sup> At the time of Arthur's death, his wife Jillian was serving on the Tufts University Board of Trustees, a position she held from 1986 to 1996.

- Raymond Sackler – a donation in 1997 to support research
- Sackler Families Collaborative Fund for Cancer Biology – a donation in 2008-09 by the Raymond and Beverly Sackler Foundation and La Fondation Sackler (Mortimer's Canadian foundation) to support research
- Richard Sackler (Raymond's son) and daughters – a donation of stock in 2009 to support an endowed research fund for a faculty member doing neuroscience research
- Raymond and Beverly Sackler Foundation – a donation in 2013 for the Sackler Lab in Convergence Research
- Arthur M. Sackler Foundation – a statue of The Buddha donated to TUSM in 2009

Richard Sackler served on the Board of Advisors of TUSM for almost two decades until 2017, when he resigned after discussions with University officials. Those discussions followed the publication of critical articles about Purdue and the Sacklers concerning OxyContin and their role in the opioid crisis in *Esquire* and *The New Yorker* magazines. *The New Yorker's* article mentioned the relationship between Tufts and the Sacklers. Richard was CEO of Purdue from 1999 to 2003. He still sits on the board of directors of Purdue, which is a private company owned by members of the Sackler family, pending final resolution of a bankruptcy case filed by Purdue. The TUSM Board of Advisors is not a fiduciary board. Rather it serves purely an advisory function to the Dean of TUSM. Richard took an active role on the Board of Advisors at times. However, we found no evidence that he ever discussed opioids or engaged in any activity to explicitly advance Purdue's business interests as a member of the Board of Advisors.

There were numerous contacts between Tufts and Sackler family members over the years. There have been ongoing efforts by Tufts, of varying levels of intensity, to steward and solicit financial donations from the Sacklers since the 1980s, continuing (though more cautious and limited) through 2017 and early 2018. Such contacts included meetings, dinners, events, correspondence and other communications with University presidents, deans of TUSM, senior

Advancement officials, and faculty members. These types of contacts would appear to be typical of what one would expect where there is an established philanthropic relationship and a university has an interest in nurturing the relationship in the hope of attracting further financial support. We did not discover any evidence of improper demands, quid pro quos, conditions on donations or grants, or improper attempts to influence or interfere with research or academic programs.

In May 2013, Tufts awarded an honorary PhD degree to Raymond Sackler. President Monaco, accompanied by other University officials, presented the degree to him in a private ceremony held at Purdue headquarters in Connecticut due to Raymond's advanced age and health concerns.<sup>8</sup>

## **B. Purdue**

Purdue has been owned and controlled entirely by members of the families of Raymond and Mortimer since Arthur's death in 1987, which was followed by the sale of his interest to the two surviving brothers. Purdue for some time has been best known as the manufacturer and distributor of OxyContin, an opioid first introduced to the U.S. market for pain relief in 1996. OxyContin was initially regarded in some medical and pharmaceutical circles as a major breakthrough in treating pain because of its time-release feature aimed at eliminating abuse. The extent of the dangers and pitfalls of this opioid were not widely known at the outset. Since then, OxyContin and Purdue have been the subject of controversy and criticism, beginning approximately early last decade when news of abuse of OxyContin first became prominent, and increasing in intensity throughout this decade. Purdue and OxyContin have received widespread

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<sup>8</sup> The Raymond and Beverly Sackler Foundation committed to a donation within four months after receipt of the honorary degree.

blame for the national opioid crisis, in particular for minimizing or covering up the risks of addiction, abuse and death while aggressively marketing the drug. Purdue has steadfastly denied that it deserves such blame.

In 2007, Purdue pleaded guilty and was thereby convicted of a felony in federal court in Virginia concerning the deceptive misbranding of OxyContin in an effort to mislead and defraud consumers and physicians between 1996 and 2001. Purdue paid a fine and compensation of over \$600 million in connection with that conviction. Three Purdue executives (non-family members) also pleaded guilty and paid fines of over \$34 million.

Civil litigation against Purdue and the Sacklers has mounted in recent years. They are facing thousands of civil suits, including actions by almost every state (some of which have been settled), as well as suits by municipalities and counties, alleging deceptive and predatory marketing practices by Purdue that contributed to the national opioid crisis. A number of complaints name members of the Sackler family as defendants, including most notably the Amended Complaint filed by Massachusetts.

Some senior administrators of Tufts, as well as Tufts Advancement officials, were or became aware (or should have become aware) of the criminal conviction and the controversy around Purdue and OxyContin at various points in time. However, there is no indication that such conviction, litigation and media coverage generated any discussion within Tufts about the relationship with the Sacklers or Purdue. We have seen no evidence of any meaningful attempt by Tufts to reconsider its relationship with, or distance itself from, the Sacklers or Purdue until autumn 2017 after some highly critical articles about Purdue and the Sacklers appeared in *Esquire* and *The New Yorker* magazines. Thereafter, Richard resigned from the TUSM Board of Advisors after a discussion with senior TUSM leaders. Tufts then proceeded with caution.

Without making any public announcements, Tufts reduced its contacts with the Sacklers and did not solicit any substantial gifts from Sackler family members or Purdue, if any at all.

Purdue has made two sets of donations to Tufts, both within TUSM: the Pain Research, Education and Policy (“PREP”) program and the Center for the Study of Drug Development. At the time of the PREP program’s establishment in 1999, Purdue was its sole outside funder. With the exception of a limited amount of scholarship funding by another donor, it continued to be the sole outside financial supporter of the program through 2008 when its funding ended. There was no outside funder after 2008.

### **III. The PREP Program**

The purpose of the PREP program was and is to provide inter-disciplinary, interprofessional, post-graduate training in pain, leading to a Master’s of Science, for health professionals from a variety of disciplines. The program was academic across a variety of disciplines. It was neither a clinical nor a research program. The original proposal was prepared internally in 1998 by TUSM faculty members (Daniel Carr and Kathryn Lasch), who were to become the program’s co-directors. The proposal was not prepared at the behest of Purdue, nor was Purdue involved in the preparation of the original proposal. The Carr/Lasch proposal received the necessary University approvals as a Master’s-level program before Tufts approached Purdue about funding in 1998. Tufts also approached and presented a proposal to at least one other potential donor, the Robert Wood Johnson Foundation, which declined to fund it.

After being approached, Purdue expressed interest. At the time, Purdue and Tufts discussed collaborating on a comprehensive pain management center at Tufts, of which PREP would have been only one part. The parties discussed a strategic partnership that would have included, inter alia, scientific research in areas of interest to Purdue and a Comprehensive

Educational Program (“CEP”) that would consist of separately funded individual projects of mutual interest. There were communications back and forth and some comments by Purdue on the proposal, but they did not go to the fundamental structure of the PREP program, nor did they relate to prescribing of opioids.

Purdue agreed to fund the proposal at \$330,000 annually for five years through 2004, broken down into \$200,000 for PREP program support, \$100,000 for CEP (special projects to be agreed upon) and \$30,000 for PREP student scholarship assistance. Purdue funded the entire amount as agreed, subject to the qualifications below. The funding agreement, executed in October 1999, included the following provisions, among others:

- *Purdue was entitled to designate one person to Tufts’ Executive Steering Committee that oversees, critiques and evaluates the program.* As matters developed, that was to be David Haddox, though it is unclear whether he or anyone else from Purdue actually filled that role. Likewise, even if a Purdue employee were officially appointed to the committee, it appears that no one from Purdue actively participated. However, Dr. Haddox acted as a liaison, of sorts, to the program on behalf of Purdue.
- *Purdue was to fund CEP at \$100,000 per year for the next five academic years, to cover specific, individual projects agreed to by Tufts and Purdue.* However, there is no indication that those projects ever occurred or were specifically funded. Instead, the money was provided for general PREP program funding.
- *Tufts and Purdue may from time to time agree to collaborate on certain research projects on pain management and related topics.* No such research projects proceeded.<sup>9</sup>
- Additional benefits to Purdue
  - *Opportunity to help develop curricula.* That apparently did not occur after PREP was launched.
  - *Presence at conferences and symposia hosted by Tufts regarding pain management.* Purdue employees may have attended several CME programs as

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<sup>9</sup> Although not a project involving Tufts or TUSM, in approximately 1999-2001 Dr. Carr, under the auspices of Tufts New England Medical Center, was the principal investigator on a relatively small research grant funded by Purdue involving a study of the effect of oral naltrexone on blocking the respiratory depressant effect of hydrocodone. The results were published in 2003 as an abstract in *Anesthesiology*, the journal of the American Society of Anesthesiologists.

well as conferences hosted by the Tufts Health Care Institute, of which Purdue was a financial supporter, in which TUSM participated.

- *Assist with marketing surveys.* While it is unclear what the parties had in mind by way of marketing surveys, this apparently did not occur.
- *Help distribute materials that Tufts and Purdue create.* Again, it is unclear what materials the parties had in mind. This apparently did not occur and there is no evidence that if materials were distributed, they related to any Purdue products.
- *Annual named lecture.* This became what was known as the Sackler Lecture. These lectures did take place and are discussed below. As of 2013, the Sackler name was no longer attached to the lecture.

After the initial five years of funding, Purdue renewed its funding in 2004 for another three years, for a total of \$500,000. The renewed funding was for program support to be used as determined by Tufts, with no strings attached. In 2007 Purdue agreed that Tufts could have another year to spend down the money. Purdue funded the entire amount as agreed. There was no additional funding of the PREP program by Purdue thereafter.

The PREP program was conceived of as, and remained primarily, a Master's-level program. However, a small certificate program also was developed within the PREP program. Seventy-five Master's degrees have been awarded since 1999. The Program is sunsetting. Approximately seven students remain who hope to finish their Master's degrees during the 2019-20 academic year. Students have been mostly mid-career health professionals in fields such as nursing, physical therapy, medicine, pharmacy, massage and acupuncture. There have been three licensed MDs, six foreign unlicensed MDs, one doctor of osteopathy and one dentist in the program. Of the 75 Master's graduates, five were licensed to prescribe medications as of the time they were in the program. A small minority of alumni went on to apply to medical school, osteopathy school or otherwise became licensed providers.

The PREP curriculum has been multi-disciplinary and interprofessional. The curriculum was not focused primarily on medications and their prescribing. While the program covered those topics, it also presented a number of other approaches to pain and wellness, including psychology, alternative healing, non-opioid medications, mindfulness, end-of-life/palliative care, pain education and various other courses. Medications and opioids were addressed in various courses, including primarily core courses in Neuroanatomy, Neurochemistry and Pharmacology of Pain and Introduction to Clinical Pain Problems, as well as Psychology of Pain and the Public Policy/Legislation Course.

The reaction of PREP alumni who were interviewed, most of whom were experienced health care professionals at the time of their enrollment, was that the curriculum was fair and balanced, with different perspectives on treatment of pain presented. They observed that opioids were not a major focus of the program. Opioids were presented in a fair and balanced way that did not raise any red flags.

The view of an expert in addiction who reviewed the curriculum and certain course materials was that the program as a whole was multi-disciplinary and the scientific aspects of medications and opioids were correctly presented, though there may have been insufficient emphasis in certain courses on the risks of opioid addiction. Furthermore, some of the language used to speak about opioids may have been generally aligned with the position of the pharma industry, without there necessarily being a causal relationship between this funding source and the use of this language.<sup>10</sup>

We fully recognize that experts may have different views as to what should be presented in such a program, as the area of pain medicine and management has been controversial. Dr. Carr

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<sup>10</sup> In particular, see the discussion of the use of the term “Opioidphobia” on page 27 below.

is a prominent advocate for treating pain as a specialty, believing that there is a human right to be free from pain, and proactively managing pain apart from any underlying disease. He has been a leading voice over the last two decades, arguing that pain, including chronic pain, has been undertreated, causing many people to suffer needlessly. Managing chronic pain may include prescribing opioids for what he would say are appropriate, carefully selected patients and circumstances under close monitoring in accordance with CDC and WHO guidelines. Dr. Carr has held that position generally since well before the establishment and funding of the PREP program, though he has modified his views somewhat over time, especially in light of the opioid crisis. In contrast, particularly in light of the opioid crisis, certain other professional experts believe that opioids should *never* be used to treat chronic pain or should *only* be used in more extreme circumstances in a more limited way.

There may well be a good-faith difference of opinion as to what is fair and balanced in an academic program that includes pain treatment. Still, there is a consensus, with which Dr. Carr agrees, that opioids have been overprescribed and that there is an “opioid crisis” that has resulted in countless deaths in the U.S. Accordingly, the primary focus of our review is not to second-guess the entire PREP curriculum, or other programs, but to determine whether there was undue or improper influence with respect to the programs. That question is discussed below.

#### **IV. Center for the Study of Drug Development**

The other program at TUSM that received some funds from Purdue is the Center for the Study of Drug Development (“CSDD”). CSDD is an independent, academic, non-profit research center at TUSM, whose mission is to provide data-driven analysis and strategic insight to help drug developers, regulators and policymakers improve the efficiency and productivity of pharmaceutical research and development. It does *not* engage in drug development or scientific

research. For example, CSDD periodically publishes a broad study, based on aggregated information, of the costs and time to bring a drug to market. It also publishes white papers and reports on a variety of topics relating to drug development, such as “Public and Private Sector Contributions to the R&D of the Most Transformational Drugs Over the Last 25 Years” and “A New Tool for Predicting Marketing Approval of Oncology Drugs.”

Initially, CSDD was funded entirely by corporate sponsorships from the pharmaceutical industry. Over the years that has changed to a combination of corporate sponsorships (approximately 24% currently), research sponsored by corporations, government, foundations, and other groups (60%) and other sources. CSDD is self-sufficient and does not depend on University funding.

Purdue has paid annual sponsorship fees totaling approximately \$380,000 since 1997 until 2010. Purdue was one of approximately 25-30 corporate sponsors in any given year. The amount that it contributed is considered in the medium range compared to that of other corporate sponsors, based on research dollars spent by corporation. Major drug companies gave in the range of \$80,000–\$110,000 annually, compared to Purdue’s total annual sponsorship contribution of \$7,000 to a high of \$40,000. Purdue did not appear to have any special influence among any of the other sponsors, nor is there any evidence of any special demands, requests or initiatives by Purdue.

CSDD performs independent research, largely economic analysis of interest to pharma companies, regulators, policymakers, economists and others, based in large part on data provided to its staff anonymously by pharma companies. The majority of the research is now sponsored research at the request of funders. Thus, to the extent they are research sponsors, pharma companies and others certainly influence the topics that are selected. But, we have no basis to

conclude that they influence the actual research or outcomes. That said, CSDD has not been a major focus of our review.

Purdue funded \$30,000 for sponsored research projects, individually in one case and as part of a group of sponsors in three cases. The one individual project was an analysis of the attrition rate (success/failure rate and causes) for the development of opioid and non-opioid pain medication. CSDD performed a typical review and analysis of its existing database and provided a report to Purdue at a cost of \$19,500. The other three sponsored research projects involved multi-company working groups in which Purdue participated, paying a participation fee of \$11,500 in one case. There is no evidence of anything unusual or improper with respect to such sponsored research. As explained to us, these projects were all typical for CSDD.

**V. Attempts to Influence or Actual Influence of Programs or Research at Tufts by Purdue or the Sackler Family**

There is no evidence of any quid pro quo arrangement whereby Purdue or any of the Sacklers agreed to fund PREP, CSDD or any other program or research in TUSM conditioned upon certain outcomes, certain curriculum being taught or certain speakers presenting in or out of the classroom. With the possible exception of the role of David Haddox, discussed below, Purdue did not appear in fact to have influenced the curriculum or instruction in the PREP program. Nor did it influence the curriculum or instruction of medical students at TUSM (who did not take courses in the PREP program) or other programs within TUSM. However, as discussed below, there is evidence that Purdue sought to obtain influence in other ways to benefit from its and the Sackler family relationship with Tufts. The question of influence may be analyzed in three categories: direct influence, indirect influence and appearance of influence.

## **A. Direct Influence**

PREP was conceived by Daniel Carr and Kathryn Lasch and subsequently presented to Purdue, after internal approval, when TUSM sought funding for the new program. It was not a program created by or solicited by Purdue. However, the October 1999 PREP funding agreement between Purdue and TUSM, executed on Purdue letterhead, provided Purdue with the *potential* for direct influence, as described above, including by having a representative on the PREP steering committee, CEP (which was not necessarily to be part of PREP program), joint research projects (also not necessarily part of PREP), input on curriculum, distribution of written materials and additional matters. In practice, we found no evidence that such potential for direct influence was exercised. Purdue did not actively participate on the steering committee, if at all; there were no joint research projects; there was no CEP program chosen or approved by Purdue; and curriculum was not approved or reviewed by Purdue, though it did have some comments on the original proposal when presented to it during funding discussions and prior to the execution of the funding agreement. We are not aware of any jointly distributed materials. Speakers for the annual Sackler Lecture were not chosen or approved by Purdue. Rather, they were chosen by Dr. Carr and covered a wide variety of topics given by a variety of speakers. Only a few even touched on or discussed medication or opioids.

Nevertheless, the 1999 funding contract was poorly drafted, overly informal and gave Purdue far too much potential influence over the PREP program. In speaking to various Tufts officials, they said flatly that such an agreement with a donor would never be approved today.

A second aspect of Purdue's direct influence involves David Haddox, a senior executive at Purdue who joined the company just as the PREP program was launching. Dr. Haddox held senior medical officer and government affairs/policy positions at Purdue. As such, he played a

significant role for Purdue in “educating” the medical profession and the public and in promoting Purdue’s perspective concerning the treatment of pain with opioids. From the early years of the PREP program until 2018, Dr. Haddox was a regular lecturer in two required courses in the program, giving one classroom lecture each semester. He did not lecture to medical students or give any classroom lectures outside of PREP. He was appointed Adjunct Assistant Clinical Professor by TUSM in 2006 and promoted to Adjunct Associate Clinical Professor in 2011, all without compensation. His appointments were handled routinely, without any special scrutiny or consideration given to the fact, one way or another, that Purdue was funding or had funded the PREP program. It should be noted that by 2008 Purdue no longer funded the program, though, as discussed above, certain members of the Sackler family made donations to TUSM for unrelated research or general support thereafter.

Dr. Haddox had extensive academic credentials and experience prior to joining Purdue and was recognized as a leader in the pain management community. So, in that respect, he was qualified to be a guest lecturer in the program. He received good reviews of his PREP lectures and students reported he was well qualified and an effective teacher/lecturer. Nevertheless, while his appointment does not appear to have been a condition to Purdue funding the program and the circumstances of his initial appointment are unclear, one can reasonably assume that it is unlikely that his initial appointment would have occurred had Purdue not funded the program. Furthermore, Dr. Haddox, as a relatively senior member of Purdue’s management team that promoted the use of OxyContin as being safe to prescribe for various types of pain, including chronic moderate to severe non-cancer pain, was positioned to further Purdue’s interests by lecturing in the PREP program.<sup>11</sup>

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<sup>11</sup> With that said, as noted above, out of a total number of 75 Master’s graduates over the 20-year life of the PREP program, only a small number and percentage of PREP alumni were licensed prescribers of medications or went on

Dr. Haddox's lectures represented the primary opportunity for direct influence. He consistently disclosed his Purdue affiliation when he lectured, so students were aware of his perspective. In the course listed as PREP 234 (Introduction to Clinical Pain Problems), Dr. Haddox gave one lecture a year on the mechanisms of pain, which by all indications consisted of appropriate, non-controversial neuroscience that did not touch on opioids. He also gave a class lecture, apparently only once or twice (in 2007 and/or 2008) on The Opioid Class of Analgesics. It generally reflected standard, accepted science. But, he did not address addiction associated with opioids in that lecture. Nor did he address side effects of the oxycodone class of drugs (to which OxyContin belongs), while he addressed side effects of other drugs. He did not mention OxyContin by name in this or any other lecture that was reported. Addiction was addressed by other lecturers but was not a major topic on its own in the PREP program.

Dr. Haddox also gave a lecture annually in PREP 235, the public policy/legislative course.<sup>12</sup> He took a historical perspective in addressing the history of drug regulation in the U.S., including in particular that of opioids. Students understood that he worked for Purdue and may have been presenting that perspective, but they generally felt that his lecture was informative and fair. There was, however, one incident in 2017 when three students in the class became upset because they felt he was sweeping the opioid crisis under the rug and that he was essentially an apologist for the pharma industry. And certain points he made analogizing regulation of opioids to Prohibition and his interpretation of regulations may be controversial. That is not to say that

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to become licensed prescribers. Therefore, if Purdue was seeking to directly influence prescribers to prescribe OxyContin for chronic pain, the PREP program was not particularly fertile ground on which to further that goal.

<sup>12</sup> Although Dr. Haddox was nominally designated as a student advisor on a single Capstone (final) project developed by a PREP student, which involved a survey of medical students' attitudes toward opioids and addiction, Dr. Haddox had very limited interaction with the student and little involvement or input in the project.

guest lecturers, who disclose their affiliations, must completely steer clear of controversial opinions.

Dr. Haddox's use of Tufts credentials reflect another aspect of what Purdue gained from the Tufts relationship. In certain articles he authored or co-authored in professional journals and publications after 2006, he listed his Tufts affiliation, together with his Purdue affiliation. Presumably he sought the adjunct appointment and promotion, and then listed those credentials, in order to obtain more credibility in presenting his views (and by extension, those aligned with Purdue).

In sum, with respect to Dr. Haddox's role as a lecturer and adjunct faculty member, it does not appear that he exercised material influence with respect to the curriculum. However, he was in the position to influence students through his classroom lectures, one or two of which in part may have reflected a point of view aligned with his employer, which was disclosed. (He also gave one or two public lectures at TUSM in 2000.) We address in our recommendations whether the University needs to consider the appropriate guidelines for an employee of a corporate donor to lecture and to have an adjunct appointment in an area in which the donor has a commercial interest, especially where the subject matter concerns public health.

## **B. Indirect Influence**

While we did not uncover evidence of an express condition, request, demand, or requirement by Purdue or any of the Sacklers concerning the Tufts academic program (except for certain provisions in the PREP agreement, which never were exercised), there appears to have been instances where they exercised influence simply by virtue of the fact that they were donors. University officials may have, consciously or not, provided favored treatment or acted in other

ways to avoid embarrassment or controversy to Purdue/Sackler or to the University by reason of the relationship.

Raymond Sackler Honorary Degree. Raymond Sackler was awarded the honor in 2013 in light of his financial contributions to Tufts and his support of convergence research. There was also the hope that he would make a major contribution of a much greater magnitude than previously. He was in his 90s and died four years later.

It is not clear how much vetting was done prior to awarding the honorary degree. The fact that he and his family were well known to Tufts, established donors and considered friends of Tufts undoubtedly affected the amount of scrutiny given to his background.<sup>13</sup> A committee of the University Board of Trustees reviews proposals for honorary degrees, and his candidacy was reviewed by the committee. A due diligence report was produced internally for the committee in accordance with normal procedure. The report mentioned briefly the controversy concerning Purdue and OxyContin, without going into any detail or mentioning the 2007 criminal conviction of Purdue. However, the committee was aware that Purdue had in 2007 pleaded guilty in a criminal proceeding related to OxyContin (though the particulars of that conviction may not have been fully understood). And, by 2013 the opioid crisis was well publicized, as was Purdue's and OxyContin's role in it. (Indeed, media coverage concerning OxyContin abuse was widespread going back as early as 1999.) Furthermore, the document nominating Raymond for an honorary degree stated he was then chairman of Purdue and active in the company. However, it appears that the committee did not probe deeply into the 2007 conviction or ongoing controversy and determined that Mr. Sackler's philanthropic contributions in support of convergence research (unrelated to Purdue's products) warranted the recognition.

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<sup>13</sup> Arthur Sackler was awarded an honorary degree by Tufts in 1984.

This award may not demonstrate any special influence of Purdue/Sackler beyond that of any other major donor of that magnitude in a university setting. But, it does raise the question of whether the University should be more searching and less deferential to donors, or potential donors, in order to safeguard its reputation and integrity. At the very least, this situation reflects a failure of adequate background checks to flag controversial issues and raise them to the highest level. There was a failure to consider in sufficient depth the appropriateness of granting an honorary degree to a principal owner of a pharma company that was in the middle of well-publicized public health crisis. Likewise, based on the information available concerning the 2007 conviction and all of the publicity and controversy relating to the opioid crisis, OxyContin and Purdue that was prominent since the early 2000s, the University should have been more intentional and cautious in its relationships with the Sackler family. Tufts should have asked more questions and engaged in considered deliberations before seeking to solicit and accept any further donations. Instead, Advancement officials continued to seek donations, with greater or lesser degrees of success, until the publicity storm hit in autumn 2017.

Dreamland. In 2015-16, a committee within TUSM decided not to assign Dreamland, a book on the opioid crisis that focused on OxyContin, was critical of Purdue's role and mentioned the Sackler family. The book had been proposed as the Common Book to be read and discussed by all incoming MD students and MPH students. While other books were suggested and only one was to be chosen, the reason that another book was selected instead of Dreamland was due, in significant part, to the existence of the donor relationship with the Sacklers and Purdue and the desire to avoid controversy regarding that relationship. This incident reflects a mindset that may have existed within Tufts, or at least among certain officials within the Advancement department (whose responsibility it is to nurture positive relationships with major donors) to give

Purdue/Sackler some deference in areas that related to their business, even without the donor having to ask for it.

### **C. Appearance of Influence**

Purdue/Sackler's philanthropic involvement with Tufts and the relationships that developed, may have created the appearance of an alignment between Purdue and the PREP program and its leadership that could have been avoided. There is little doubt that Purdue was, at minimum, seeking to benefit from its association with Tufts. While Tufts did not share Purdue's goals, it nevertheless was drawn closer to Purdue in ways that created questions about the relationship.<sup>14</sup>

As the co-founder and co-director, then sole director, of the PREP program, Dr. Carr was particularly vulnerable to such appearances stemming from the Purdue relationship. Dr. Carr is and has been since before the establishment of PREP an eminent leader in pain medicine and a passionate advocate for the active treatment of chronic pain through a multi-dimensional approach, including, where appropriate, opioids prescribed in accordance with existing professional and government guidelines, as well as alternatives to opioids. It should also be noted that for approximately a six-year period, Dr. Carr left the directorship of the PREP program to become CMO and then CEO of Javelin Pharmaceuticals, Inc., whose main product was a non-opioid analgesic intended to reduce the need for traditional intravenous opioids to address post-operative pain. Nevertheless, given his position in the PREP program, his strong views on

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<sup>14</sup> Ironically, Purdue's funding of the PREP program was not widely publicized. Program materials did not mention Purdue's sponsorship. At one point, the website did make mention of Purdue. PREP alumni from various periods whom we interviewed were not aware of the Purdue funding until recently and, in at least one case, not until the interview. One alumnus stated that may have affected his view of the program had it been made known at the time. That raises the question of transparency and whether Purdue may have sought influence while keeping its involvement below the radar. On the other hand, the funding agreement and discussion leading up to the agreement did contemplate joint materials that would have publicized the relationship, so it did not appear that Purdue requested secrecy about its funding role.

the need to treat chronic pain, and the financial support of Purdue, Dr. Carr often found himself in a position of agreeing with Purdue and doing his best to accommodate Purdue and the Sacklers. We do not find that, as result, he violated any University policies or compromised his own beliefs. However, it would have been the better course to maintain further distance from Purdue than he did, as described below.

1. Carr appeared in a Purdue print advertisement in 2002, for which he was not paid. The ad publicized the fight against prescription abuse and Purdue's claimed role in that. The ad did not mention OxyContin or promote or mention any Purdue product or class of products. There was a photo of Carr in his white lab coat, and his affiliation with Tufts was prominently mentioned. Before agreeing to appear in the ad, Carr appropriately sought approval from his department heads at TUSM and TMC, as well as the Dean of TUSM, all of whom approved. Indeed, a senior TUSM official commented that the ad would be good publicity and a good gesture toward Purdue. While the ad did not promote a product, it reflects an uncomfortable, inappropriate association with a commercial financial supporter. It also gave some credibility to Purdue's claim to be fighting opioid abuse. Although no then-existing Tufts policies were violated, better judgment should have prevailed.

2. In 2002, Purdue had asked Dr. Carr to testify in its designated slot before an FDA Advisory Committee concerning restriction of manufacture or prescription of, or access to, controlled substances used in an appropriate medical setting to relieve pain. Carr opposed such barriers, as did Purdue. Carr ultimately did not testify. Purdue had asked him to testify as a consultant. After obtaining advice from Tufts counsel, Carr did not sign a consulting agreement for various reasons, among which was his expressed concern that testifying as a consultant might diminish the strength of his testimony. He also said that he did not want to receive an honorarium

or expenses for his testimony, were it to occur. However, the university's advice to Carr to not testify as a consultant was not made on the grounds that testifying would be inappropriate.

In the same time frame Carr wrote an email to Richard Sackler in December 2001, in which he said: "Our continued collaboration is a top priority for me.... Re: FDA, the whole OxyContin/regulatory discussion hinges on whether we blame ourselves, or the perpetrators who victimize us, for their harmful misdeeds." Thus, while Carr ultimately turned down the opportunity to testify, this episode reflects another way in which Purdue sought to leverage its relationship with Tufts. It also reflects an overly close entanglement or identification with Purdue and an effort to please Purdue and the Sacklers.

3. In May 2000, Purdue forwarded Carr's name to its outside PR firm as a possible spokesperson for Purdue. There is no evidence that this went any further, that Carr responded or that Carr was even consulted before his name was forwarded.

4. Purdue sponsored a TUSM Continuing Medical Education Program in Maine on at least three dates in 2000 on "Appropriate Use of Opioids." The panel was led by Carr and included non-industry experts such Dr. Seddon Savage from Dartmouth and John Crowley from the Federal Drug Enforcement Agency. Purdue paid \$78,354 as an unrestricted educational grant, which is disclosed in the program.

5. Carr met, or at least agreed to meet, with certain senior Purdue marketing employees in August 2004. Other than for the purpose of accommodating a corporate donor, it is unclear what appropriate academic or scientific purpose such meeting would have furthered.

6. Carr wrote to a colleague in Australia in 2001 that Purdue is "very preoccupied with Oxycontin witch-hunt in U.S." and referred to the latest article on the subject appearing on the front page of *The New York Times* as "fairly hysterical and pejorative." In general, in the first

half of the last decade, before the opioid crisis was widely recognized but after Purdue had begun to come under scrutiny and criticism over OxyContin, Carr at times appeared to be sympathetic to Purdue when it was subject to criticism, and sought opportunities to collaborate in fighting “Opiodphobia,” which he viewed as an irrational fear of prescribing opioids for chronic pain under any circumstances. While it likely reflected a convergence of interests and beliefs (at that time, Carr thought that what Purdue was doing was in the interests of what he passionately believed in for a long time, that chronic pain was being undertreated), these comments suggest that he was too closely identified with Purdue, the sponsor of the PREP program he founded and directed. We are not suggesting that he was in any way induced or directed to take such a position. But, a greater degree of circumspection would have been appropriate.

Indeed, the use of the term “Opioidphobia” was not isolated to emails or other informal communication. That term appeared in certain PREP course materials. The use of the term is problematic in that it carries the risk of stigmatizing prescribers for being cautious, thereby potentially skewing prescribing decisions in ways not aligned with the regulatory structure intended to balance the benefits and risks of opioids.

7. In a March 2003 email, Carr asked Richard Sackler about his availability to discuss the shape/evaluation of the PREP program and said he may “become involved with potential projects with Purdue,” such as CME programs sponsored by Purdue through professional associations, “that ideally would build on what we’ve invested in our Tufts curriculum.” Sackler wrote a month later that he had some ideas to share about the program going forward. However, there is no indication that the exchange went further. But, Carr indicated that he was willing to help Purdue, though not eagerly, with some issues that it was having with a CME program it was sponsoring, in the hope of generating goodwill for PREP. Carr states that he was just being polite

and responsive to the sponsor of the PREP program. But, it certainly carries the risk of undue involvement by the sponsor in the program. However, Carr firmly states that neither Purdue nor Sackler had any input into the PREP program.

8. Purdue tried to use the relationship with Tufts to its advantage. There are various examples in addition to those discussed above. For example, on at least one occasion, in the early years of PREP, Purdue attempted to utilize Haddox's relationship with Tufts to obtain information on CME programs (sponsored by Tufts Health Plan, not TUSM) relating to the OxyContin crisis. Years later, in 2016, Purdue sought to enlist Tufts to file an amicus brief in support of Purdue's position in a patent litigation appeal not relating to OxyContin. Tufts administration declined Purdue's request, as there was no compelling University interest in the issue, notwithstanding that, from a development perspective, it would have been good for donor relations.

In general, the allegations of the Massachusetts Attorney General's Amended Complaint suggest that Purdue and, in particular, certain marketing and related personnel, were interested in leveraging relationships within TUSM and were claiming to be realizing some success. It is difficult for us to assess Purdue's intent or whether any of these internal Purdue documents reflect a certain degree of puffing. We can say that some of what they were discussing did not involve Tufts or TUSM. More importantly, if certain Purdue employees expressed satisfaction with the efforts to develop certain relationships at TUSM (principally through Haddox's role), that did not manifest itself in specific influence that we have found, other than as discussed herein.

## VI. Compliance with Tufts Policies

Tufts' policies, including conflict-of-interest policies, going back to 1999 were limited and not well documented or preserved. But even comparing the conduct described above to existing policies, we have not discovered any conduct that would constitute a clear violation of policy. With that said, the PREP funding agreement would not pass muster today under Tufts' Gift Agreement policy, if it were applicable, due to control left with Purdue as described above.<sup>15</sup>

We did not discover evidence of any individual wrongdoing. While there may have been a convergence of certain views by PREP leadership and attempts to accommodate donors, there was no financial wrongdoing or unauthorized conduct. Nor was there any agreement or apparent effort to make any modifications, additions or omissions to the academic program to benefit Purdue as the sponsor.

We believe, however, that some of the conduct violates the spirit of the current University Gifts Policy Statement and the current grant process. The current Gifts Policy Statement explicitly states that no gift will be accepted that “in any way compromises academic freedom and the rigorous and independent pursuit of truth” and prohibits direct donor involvement in the administration of a gift, though some advisory, consultative involvement may be acceptable with the approval of the VP for University Advancement. Certainly, the PREP funding agreement *on its face* contemplates substantial involvement by the donor. While this does not appear to have occurred, the agreement should never have been signed by Tufts.

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<sup>15</sup>The PREP agreement would apparently be treated as a grant today. In any event, if not a sponsored research contract – which it was not – control over academic program or research is to remain solely with Tufts, whether the donation is considered a gift or a grant.

Moreover, certain of the conduct described above creates the appearance of donor involvement and influence that is inconsistent with the spirit of this policy.

## **VII. Recommendations**

We are making the following recommendations for consideration by the University's Administration, Board of Trustees and relevant departments. They are not generally intended to be prescriptive, but rather to generate careful thought and deliberation to ensure that the University maintains its reputation as a leading research and teaching university while safeguarding its academic integrity, independence, ethical standards and financial stability. We certainly do not suggest that relationships with corporate donors or their employees are to be categorically avoided, even in the classroom. Indeed, practical expertise that arises from such relationships can be mutually beneficial. But, our overriding theme is that there is a greater need for specific guidelines, due diligence, careful review, and transparency.<sup>16</sup>

### **A. Consider formalizing and enhancing the review of potential conflicts of interest or controversies created by donations or proposed donations**

1. Creation of a high-level University Gifts Policy Committee to review major gifts or grants above a certain size (e.g., \$250,000 per donation or in the aggregate) that raise questions of conflicts of interest, reputational risk for the University or other controversy. Major naming gifts should be included in this category. The Committee might include senior members of the administration, Advancement, General Counsel, senior school representatives, board of trustees members, an ethics expert and faculty representatives, consistent with maintaining appropriate confidentiality. It would create a formal process to support the President and other senior University officials and foster more consistency and continuity in addressing often difficult decisions that could have a significant impact on the reputation of Tufts.
2. Heightened review process, incorporating due diligence guidelines, for major gifts above a certain threshold in general. Even if a potential donation on its face may not appear to be controversial or raise a conflict of interest, heightened review of

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<sup>16</sup> We are not making a recommendation on whether to remove the Sackler name from the Sackler School or the TUSM building, because it was not within the scope of our engagement. The decision on whether to remove the names is within the purview of the University Board of Trustees.

a major donation is advisable given the potential impact on the University. Due diligence guidelines should be applied to both new and existing donations above a certain amount. There do not appear to be standard processes in place for reviewing a donor's background. Furthermore, once someone is known to the University, and in particular an existing donor, there is generally less follow-up. There appears to have been a prevailing attitude that if someone is known to Tufts (e.g., an alumnus or existing donor), a gift from that person does not require much scrutiny, whereas a major gift from someone not previously affiliated with Tufts may bear greater scrutiny. However, circumstances may change over time for any particular donor, so rigorous due diligence is called for in the case of any major gift, particularly a naming gift that could bring significant attention. There are third-party providers of such services that Tufts has begun to utilize and whose expanded use should be encouraged. In addition, greater expertise and capacity should be developed internally.

3. Heightened scrutiny with respect to donors, corporate funding and other matters in certain sensitive circumstances, such as where there is a public health crisis, or where the area of academic training or research has a particular impact on individuals' or society's well-being. This may be particularly relevant to TUSM, the Dental School, the Friedman School of Nutrition, the Cummings School of Veterinary Medicine and the Sackler School.
  4. Anonymous gifts (above the threshold) should only be accepted if agreed to by the University Gifts Policy Committee. The purpose of this recommendation is not to prohibit anonymous gifts made in good faith out of legitimate concern for anonymity. Rather, it is intended to probe whether the reason for requesting anonymity is warranted and consistent with the values of the University. It will also ensure that the decision to accept such gifts is elevated to the appropriate level.
- B. The University should adopt and publish clear standards for acceptance of major donations.** We recommend that Tufts establish standards and guidelines for major gifts, making clear to donors and the public what restrictions, if any, it will accept. Also, the process of accepting such gifts, including the role of the Gifts Policy Committee, should be made clear. Any exceptions to those standards and guidelines should be made sparingly and must be approved by the University Gifts Policy Committee.
- C. Appointment of a University Compliance Officer.** In higher education today, compliance issues are more and more complex, risky and time-consuming. Currently compliance responsibilities within Tufts are diffuse, spread among, inter alia, the Office of University Counsel, Associate Vice Provost for Research Compliance in the Office of Vice-Provost for Research and the Assistant Dean for Conflicts of Interest Management in TUSM, who spends a relatively small portion of her time with respect to those responsibilities and whose review has a limited purview. Centralization and additional resources should be considered to better coordinate this critical function.

- D. **Establish an Institutional Conflict-of-Interest Policy.** The formal conflict-of-interest policies of TUSM and the Office of the Vice Provost for Research cover research and individual conflicts of interest of faculty members and principal investigators, primarily of a financial nature. However, there do not appear to be clear guidelines that cover conflicts of interest that the institution may have in accepting gifts, grants or research dollars or where the receipt of such funds has the potential for institutional or reputational harm. At the same time, conflict-of-interest policies should be expanded to apply clearly to academic programs and curriculum, not just research.
- E. **Establish a formal University grants policy, parallel to the University gifts policy statement, in particular with respect to academic freedom, independence and donor influence.** Ensure uniformity of gift, grant, and donor agreements to the greatest extent possible. Such agreements must make absolutely clear to the donor that it is to have no control or influence over research or academic programs. Furthermore, agreements which on their face provide for naming rights in perpetuity should be avoided to the extent possible by limiting the number of years (especially for facilities) and by including opt-out clauses based on conduct or materially changed circumstances.
- F. **Increase awareness of and adherence to conflict-of-interest policies.** Existing conflict-of-interest training and review for students and faculty in TUSM is currently minimal (one-time, one-hour total) and not subject to annual review. It seems that many regard it as perfunctory. We suggest a review of conflict-of-interest training and requirements for faculty and students. We further suggest that University conflict-of-interest and related policies be better publicized, integrated and made more accessible. Policies are spread out among various segments of various University websites, not easily found and not well known. In the course of our review, even with the assistance of various University officials, it was often difficult to identify and locate relevant policies.
- G. **Review TUSM Curriculum Concerning Conflicts of Interest and Industry.** Several of the students and faculty we interviewed expressed a concern that there is insufficient attention in the classroom to the discussion of broader conflict-of-interest issues. For example, in the context of the pharmaceutical industry, which was the focus of our review, some believe that the competing ideas and public policy concerns about the opioid crisis and the role of pharma were not adequately discussed and debated. Others disagree and maintain that these issues were discussed. In our view, at the very least, it is important that the role of pharma and the process of drug development and marketing be openly discussed and debated so that future doctors understand the realities that they will face once they are practicing and licensed to prescribe medications. We suggest a review of the curriculum with these factors in mind.
- H. **Avoidance of Conflicts of Interest, Appearance of Conflicts of Interest and Controversies in Specific Contexts**
1. A policy and formal process on faculty or teaching appointments for employees of corporate donors in areas related to the grantor's business. This might be tailored

to the nature of the business and academic field, but it is of particular concern where the corporate business and the subject involve public health and welfare. At minimum, if a strict policy proves to be too difficult or impractical to implement, there should be a process that ensures heightened scrutiny that carefully assesses such a conflict of interest where an employee of a corporation involved in an industry impacting public health and welfare (such as pharma, medical devices, tobacco, etc.) seeks a faculty appointment in an area related to that business.

2. A policy providing that an academic program (as opposed to research) should not be sponsored by a corporate funder in an area related to the corporation's business, particularly in matters related to public health. At the very least it creates the appearance of undue influence. To the extent that there is a corporate funder of an academic program, there should be a minimum number of private funders, so that a single company should not be the predominant funder of any academic program.
  3. University officials or faculty should not appear in donor, grantor or sponsor advertisements, commercials or other promotional material with Tufts affiliation identified.
  4. Establish guidelines or standards governing contact by University officials or faculty in connection with their duties with sales or marketing personnel of a corporate donor, whether for training, funding, discussing research, curriculum or otherwise. The goals of corporate marketing personnel and the academic, clinical training, research and public health missions of the University, particularly within TUSM, the Dental School, the School of Nutrition, and the Veterinary School, are generally not aligned. For example, TUSM already bars pharma and medical device marketing personnel from any contact with medical students on campus. Any guidelines should be based on the circumstances and issues faced by the particular school in question.
  5. Stronger limitations on speaking or giving presentations at corporate donor premises and conferences. We recognize that flat prohibitions are difficult, if not impossible, to enforce for a variety of reasons. However, such presentations pose the risk of creating unfortunate conflicts of interest or appearances of conflicts of interest. Clearer policies and processes to manage such situations should be considered.
  6. Review of guidelines as to the circumstances where faculty can use their Tufts affiliation in commercial settings or to promote the interest of commercial enterprises.
- I. **Greater transparency in disclosing funders of a program or research.** Each of the PREP alumni interviewed said that he or she had not been aware at the time they matriculated that Purdue sponsored the program, and certain of those alumni said they would have wanted to know that fact. The identity of a principal financial sponsor may reflect on the perception of the program and the value of degrees awarded.

- J. **Clarifying and better publicizing the University's reporting/whistleblowing structure.** In addition to existing applicable policies and procedures that provide avenues for reporting, the University maintains a confidential hotline (also available on-line) which is the designated confidential reporting mechanism for a variety of issues, concerns or situations, whether employment related, personal conduct, academic integrity, conflicts of interest, or otherwise. However, given its broad scope, it may benefit from clarification and greater publicity. The appointment of a Chief Compliance Officer may help in this regard.
- K. **Due Diligence for Honorary Degrees.** Ensure that rigorous due diligence is consistently performed with respect to honorary degree candidates, whether or not they have an existing relationship with the University.